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| 09/810,186      | 03/19/2001  | Chieko Ohsumi        | 204934US0           | 6978             |

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OBLON SPIVAK MCCLELLAND MAIER & NEUSTADT PC  
FOURTH FLOOR  
1755 JEFFERSON DAVIS HIGHWAY  
ARLINGTON, VA 22202

EXAMINER

COLLINS, CYNTHIA E

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1638

DATE MAILED: 07/16/2002

17

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/810,186

Applicant(s)

OHSUMI ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election with traverse of Group II in Paper No. 16 is acknowledged. The traversal is on the ground(s) that the claims of Groups I, III and IV are directly dependent from the claims of Group II by virtue of the present amendment, and as such it is improper to separate the claims. The traversal is also on the ground(s) that no adequate reasons and/or examples have been provided to support a conclusion of patentable distinctness between the Groups, and on the grounds that a search of all the claims would not constitute a serious burden on the Office. This is not found persuasive because dependent claims may be properly restricted even though they depend from the same independent claim, and because all the methods as originally claimed could be practiced using patently different methods, as explained in more detail in the restriction requirement mailed April 8, 2002. However, because the only method exemplified in the specification is a method in which a nucleic acid encoding a raffinose synthase is introduced into a plant, the restriction requirement is withdrawn, and claims 1-7 are examined on the merits in the instant office action.

### ***Claim Objections***

Claim 1 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 is dependent on claim 5, which is not a previous claim.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3 and 4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The claims are drawn to a method of increasing stress resistance to a plant which comprises increasing raffinose content in the plant body by introducing a raffinose synthase gene into the plant body.

The specification describes a single method of increasing drought stress resistance to a plant by introducing into and expressing in an *Arabidopsis* plant an isolated nucleic acid of SEQ ID NO:2 obtained from soybean that encodes a raffinose synthase polypeptide of SEQ ID NO:1 (Example 1 pages 18-25 and Figures 1-3). This does not constitute a substantial portion of the genus that comprises a raffinose synthase gene. The claimed genus encompasses a multitude of different nucleotide sequences and proteins, including those yet to be discovered. The disclosure of a single nucleotide sequence that encodes a soybean raffinose synthase polypeptide that confers drought stress tolerance when expressed in *Arabidopsis* does not provide an adequate description of the claimed genus, and in view of the level of knowledge and skill in the art, one skilled in the art would not recognize from the disclosure that the applicant was in possession of

the claimed genus (see Written Description Guidelines, Federal Register, Vol. 66, No. 4, January 5, 2001, pages 1099-1111).

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for increasing drought stress resistance in a plant by introducing into a plant and expressing an isolated nucleic acid of SEQ ID NO:2 encoding a raffinose synthase amino acid sequence of SEQ ID NO:1, does not reasonably provide enablement for methods for increasing stress resistance in general, or methods of increasing stress resistance in a plant by introducing into a plant and expressing other isolated nucleic acid sequences encoding other amino acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are drawn to a method of increasing stress resistance to a plant which comprises increasing raffinose content in the plant body, a method of increasing stress resistance to a plant which comprises increasing raffinose content in the plant body by introducing into a plant a raffinose synthase gene, a method of increasing stress resistance to a plant which comprises increasing raffinose content in the plant body by introducing into a plant a raffinose synthase gene encoding a protein of SEQ ID NO:1, or a protein having raffinose synthetic activity and comprising an amino acid sequence that differs from SEQ ID NO:1 by deletion, substitution or addition of at least one or more amino acids, and a method of increasing stress resistance to a plant which comprises excessively expressing in a plant a protein of SEQ ID NO:1, or a protein having raffinose synthetic activity and comprising an amino acid sequence

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that differs from SEQ ID NO:1 by deletion, substitution or addition of at least one or more amino acids.

The specification discloses method of increasing drought stress resistance to a plant by introducing into and expressing in an *Arabidopsis* plant an isolated nucleic acid of SEQ ID NO:2 obtained from soybean that encodes a raffinose synthase polypeptide of SEQ ID NO:1 (Example 1 pages 18-25 and Figures 1-3). The specification does not disclose whether this method results in increased resistance to stresses other than drought stress. The specification also does not teach amino acid deletions, substitutions or additions that can be made to SEQ ID NO:1 such that the altered polypeptide retains raffinose synthetic activity, and such that the altered polypeptide confers stress resistance to a plant when excessively expressed. Additionally, the specification does not teach the expression of other isolated nucleic acids that encode raffinose synthase and increase stress resistance. Furthermore, the specification does not teach other methods of increasing raffinose in a plant, or other methods of excessively expressing raffinose synthase in a plant, such that stress resistance is increased.

While one of skill in the art could readily make transgenic plants expressing a recombinant polypeptide of SEQ ID NO:1 encoded by an isolated nucleic acid of SEQ ID NO:2, it would require undue experimentation for one skilled in the art to determine how to express SEQ ID NO:1 in a manner that would increase resistance to stresses other than drought, because the specification does not teach the level of raffinose synthase or raffinose required to confer resistance to stresses other than drought. Also, while one of skill in the art could readily make amino acid deletions, substitutions or additions to SEQ ID NO:1, it would require undue experimentation for one skilled in the art to determine which amino acid deletions, substitutions

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or additions to make in SEQ ID NO:1 such that the altered polypeptide retains raffinose synthetic activity and confers stress resistance to a plant when excessively expressed, because the specification does not teach which amino acid deletions, substitutions or additions to make. To claim all modifications without any guidance as to how inoperable embodiments can be readily identified and eliminated other than by trial and error is an initiation to experiment requiring undue experimentation. Additionally, while one of skill in the art could readily make transgenic plants expressing other raffinose synthases, it would require undue experimentation for one skilled in the art to determine which raffinose synthase to express and at what level, because the specification does not teach which other raffinose synthases to express and at what level to confer resistance to stress. Furthermore, while one of skill in the art could readily increase raffinose or excessively express raffinose synthase by other methods, it would require undue experimentation for one skilled in the art to determine how much to increase raffinose, and how much to excessively express raffinose synthase to confer resistance to stress, because the specification does not teach other methods of increasing raffinose in a plant, or other methods of excessively expressing raffinose synthase in a plant, such that stress resistance is increased.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7 are indefinite in the recitation of "increasing" or "increased". "Increasing" or "increased" are relative terms that lack a comparative basis.

Claim 1 and 2 are indefinite in the recitation of "raffinose synthase gene". The word gene implies DNA existing in nature that includes coding regions and noncoding regions, such as enhancers, promoters, and introns. It is suggested that the claims be amended to recite "isolated nucleic acid encoding a raffinose synthase".

Claims 2, 4, 6 and 7 are indefinite in the recitation of "raffinose synthetic activity", as "synthetic" may imply a particular method of making. It is suggested that the claims be amended to recite "raffinose synthesis activity" for clarification.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 5 recites no method steps at all. In the absence of method steps, one would not know how to increase raffinose content in the plant body in order to increase stress resistance. Furthermore, the claimed method does not result in an increase in stress resistance to a plant as set forth in the preamble.

Claims 4 and 6 are indefinite in the recitation of "improving" or "improved". "Improving" or "improved" are relative terms that lack a comparative basis. It is also unclear in what way raffinose synthetic activity is improved.

Claim 7 is indefinite in the recitation of "excessively expressing". "Excessively expressing" is a relative term that lacks a comparative basis.



Claim 7 is indefinite in the recitation of "(c)" and "(d)", because claim 7 recites no subparts (a) and (b). It is suggested that the claim be amended to recite (a) and (b) in place of (c) and (d).

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Bachmann et al. (1994, Plant Physiology, Vol. 105, pages 1335-1345).

Claim 5 is drawn to a method of increasing stress resistance to a plant which comprises increasing raffinose content in the plant body.

Bachmann et al. teach a method of increasing stress resistance to a plant which comprises increasing raffinose content in the body of *Ajuga reptans* plants by cold acclimation (Table II page 1340).

***Remarks***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210.

The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the

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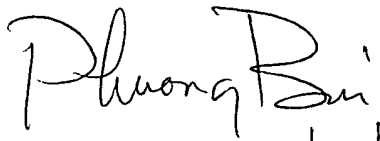
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organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC  
July 15, 2002

  
PHUONG T. BUI  
PRIMARY EXAMINER 7/15/02